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510(k) Summary

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Mitek Products is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Mitek Products chooses to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the modified device, Mitek CuffTack is as follows:

Trade Name: **Mitek CuffTack**

Sponsor: Mitek Products
249 Vanderbilt Avenue
Norwood, MA 02062
Registration #1221934

Device Generic Name: Bone Anchor

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Product Code: 87 MAI (21 CFR 888.3030)

Predicate Devices: **K994269 – Mitek Titan RC Tack**
K973009 – Mitek Non-absorbable"H" Fix

Device Description: The device described in this 510(k) is sterile, disposable implant designed to secure soft tissue to bone. The Mitek CuffTack is indicated for use in the following procedures for reattachment of soft tissue to bone: Shoulder: Repair of rotator cuff tears.

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the Mitek CuffTack has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 7 2000

Ms. Christine Kuntz-Nassif
Senior Regulatory Affairs Associate
Mitek Products
c/o Ethicon, Inc. A Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K003076
Trade Name: Mitek Cufftack
Regulatory Class: II
Product Code: MAI
Dated: October 02, 2000
Received: October 03, 2000

Dear Ms. Kuntz-Nassif:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003076

Device Name: Mitek CuffTack

Indications for Use:

The Mitek CuffTack is indicated for use in the following procedures for reattachment of soft tissue to bone: Repair of rotator cuff tears.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003076

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801.109)